Methods: Pts enrolled in TITAN had symptomatic CHF, FMR ≥2+, enlarged LV's and low EF's. After placement of CMCS, cor angio was done immediately to look for cac. If no cac, and there was an improvement in MR the device was released, otherwise it was recaptured. Cine films were reviewed for the presence or absence of ca cross. Patients who had ca cross were compared with patients without ca cross for clinical and echo changes at 6 month follow-up.
Results: 53 pts were enrolled in Titan, with 36 receiving implants. In 34 pts (64%) a coronary artery was crossed. Of the 17 pts without implants 8 pts had the device removed at least in part due to cac, thus 15% of implants were limited by cac. No patient had an MI within 30 days of the procedure. 7 pts had chest pain with FU to one year, 12% w crossing vs 16% without (NS). 5 pts had cor angios, with none showing CMCS-related coronary artery compromise. 11 pts died with FU (includes non-implanted pts): 18% w ca cross vs 26% wo (NS). No echo or clinical differences were seen in FU between those w vs wo ca cross (Table), except for reduced MR at 6 month FU in patients with coronary artery crossing.

Echo and Clinical Comparisons between patients with a crossed coronary artery and those without

	MR Baseline	MR 1 mo	MR 6 mo	NYHA Baseline	NYHA 1 mo	NYHA 6 mo	6 MWT Baseline	6 MWT 1 mo	6 MWT 6 mo
+ ca Cross	2.7±0.7	1.9±1.0	1.1±1.1	3.1±0.2	1.9±0.6	1.9±0.7	312±77	414±145	473±247
- ca Cross	2.9±0.5	2.1±0.9	2.2±0.6*	3.1±0.2	2.2±0.8	2.2±0.6	292±70	386±160	395±157
*P<0.05 compared with + ca cross									

Conclusions: Similar to the findings in AMADEUS, coronary artery crossing is common when using the CMCS, but infrequently limits successful deployment, and does not appear to have any impact on medium-term safety or efficacy.

Plenary Session XVIII
The Best of the Best TCT 2010 Abstracts
Main Arena
Friday, September 24, 2010, 2:50 pm – 3:30 pm
(Abstract Nos 105-107)

TCT-105

Three-year Follow-up Of The Syntax Trial: Optimal Revascularization Strategy In Patients With Left Main Disease

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Background: Percutaneous coronary intervention (PCI) is an increasingly common revascularization strategy for patients (pts) with left main (LM) stenosis. Recently, ACC/AHA PCI guidelines upgraded unprotected LM PCI to a class IIb indication. Long-term follow-up data in LM pts have been limited. This analysis will examine 3-year outcomes of LM pts in the SYNTAX trial.
Methods: SYNTAX randomized pts with *de novo* 3 vessel (3VD) and/or LM disease to PCI with TAXUS Express stents or coronary artery bypass surgery (CABG) if suitable for equivalent revascularization using either treatment. Analysis of the LM cohort was prespecified and sufficiently powered.
Results: Two-year MACCE (major adverse cardiac and cerebrovascular events) was similar in LM PCI and CABG-treated pts (CABG 19.3% vs PCI 22.9%) as was death/stroke/MI (11.8% vs 10.2%; Table). Stroke was significantly increased in the CABG group (2.4% vs 1.2%, *P*=0.01) and repeat revascularization was increased in the PCI arm (10.4% vs 17.3%, *P*=0.01) at 2 years (Table). MACCE was similar between groups in pts with lower SYNTAX Scores (0-32: 20.5% vs 18.3%, *P*=0.48) but significantly increased in PCI pts with high scores (33+: 17.8% vs 29.7%, *P*=0.02). Outcomes at 3-years will be available and presented for the first time.

Adverse Event Rates in the LM cohort at 2 years						
		CABG	PCI		CABG	PCI
2-year Rates	MACCE	19.3	22.9	Stroke	3.7	0.9*
	Death/Stroke/MI	11.8	10.2	MI	4.1	5.5
	Death	6.2	5.6	Repeat Revascularization	10.4	17.3*

MACCE: All-cause death, stroke, MI, repeat revascularization. Time-to-event rates at 2 years. *P<0.05 from log-rank or chi-square test.
Conclusions: Positive outcomes from SYNTAX and other recent studies of LM disease suggest PCI using drug-eluting stents may be as effective but less invasive than CABG in certain subsets of pts. The three year data to be presented will continue to clarify the role of PCI relative to CABG for the treatment of patients with LM disease.

TCT-106

Quality of Life for Patients Undergoing Percutaneous Vascular Intervention for Claudication vs Critical Limb Ischemia, Insights from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium

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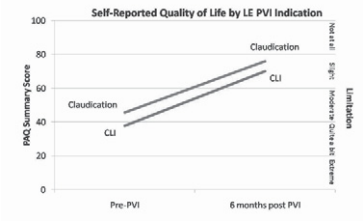
Background: Lower extremity percutaneous vascular interventions (LE PVIs) are generally performed to improve the quality of life (QoL) of patients with symptomatic peripheral arterial disease (PAD). We sought to evaluate and compare the baseline and 6 month post-intervention QoL in patients who underwent PVI for either claudication or critical limb ischemia (CLI).
Methods: QoL data were assessed at baseline and 6 months using the Peripheral Arterial Questionnaire (PAQ) for 1667 PVI patients in a multicenter, multidisciplinary regional consortium. Analysis of variance was employed to compare temporal change in QoL based on indication for LE PVI (Claudication vs CLI).
Results: (See graph). There were 1037 patients in the claudication group and 630 patients in the CLI cohort. The mean age was 68 (± 11) years, and did not differ between groups. More CLI patients were women (47 vs 41%; p<0.02). Insulin requiring diabetes was more common in the CLI cohort (31 vs 15%; p<0.0001), as was dialysis (5.6 vs 1.7%; p<0.0001). At baseline, patients with CLI reported lower overall QoL than patients with claudication (p<0.0001). At 6 months, the claudication indication for PVI patients reported a better QoL than CLI indication patients (p<0.0001). The improvement in QoL from baseline to 6 months post PVI was equivalent in both groups (p=0.2).



Conclusions: The QoL of all patients referred for LE PVI is severely impaired, particularly in those patients with CLI. LE PVI for patients with either claudication or CLI is associated with equivalent and dramatic improvement in QoL that is sustained for at least 6 months post intervention.

TCT-107

EVEREST II Randomized Clinical Trial: Clinical Benefit by MR Grade in Patients One Year following Successful MitraClip Therapy

James Hermiller[1], Saibal Kar[2], Michael Rinaldi[3], Peter Fail[4], Scott Lim[5], Richard Smalling[6], William Gray[7], Andrew Wang[8], Howard Herrmann[9], Jason Rogers[10], John Lasala[11], Tanvir Bajwa[12], Paul Grayburn[13], Wesley Pedersen[14], Brian Whisenant[15], Andrew Berke[16], Michael O'Donnell[17], Patrick Whitlow[18], Robert Siegel[2], Alfredo Trento[2], Donald Glower[8], Ted Feldman[19], Elyse Foster[20], On Behalf of the EVEREST II Investigators
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Background: EVEREST II is a prospective, multi-center, randomized controlled trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of mitral regurgitation (MR). Measures of 12 month clinical benefit, defined as improvements in LV function and symptomatic improvement, were evaluated for the Device Group and Control Group, and have been previously reported. Observed clinical benefit by 12 month MR grade has not been reported. These data are important to understanding the therapeutic potential of the MitraClip procedure.
Methods: Twelve month clinical benefit observed in patients with ongoing clinical success (defined as acute procedural success with MR ≤2+ at discharge and continued MR reduction ≤2+ at 12 months) in the Device group is reported. Measures of clinical benefit include echocardiographic measures of LV function, NYHA functional class, and Quality of Life scores. Additional analyses of clinical benefit are reported for Device group patients stratified by 12 month MR grade. Comparisons will be made with the overall Device Group and Control Group.
Results: Significant improvement in LV function, NYHA Functional Class, and Quality of Life scores was observed for all Device patients with ongoing success (MR≤2+ at 12 months). Patients with MR reduced to 1+, 1+ to 2+, or 2+ at 12months demonstrated marked clinical benefit, with significant improvements noted from baseline to 12 months. A detailed analysis of these data will be presented.

12 Month MR Grade	Duration	LVEDV (ml)	LVESV (ml)	NYHA Class I/II (%)	PCS Score	MCS Score
MR≤1+ (n=41)	Baseline	156.3±35.5	66.1±24.2	40	40.6±9.3	46.6±11.2
	12 months	126.5±32.9	55.6±24.7	100	44.8±8.3	53.3±7.6
MR 1+ to 2+ (n=14)	Baseline	144.5±36.0	56.1±19.4	78.6	43.7±9.1	49.5±10.4
	12 months	134.5±28.5	58.0±21.8	100	48.9±9.7	52.6±4.8
MR = 2+ (n=39)	Baseline	152.4±34.3	58.6±21.7	48.7	40.6±10.4	46.9±11.7
	12 months	134.4±33.8	57.2±22.5	94.9	45.9±10.1	53.7±7.5

*Remaining patients: 6 died, 9 underwent surgery, 6 withdrew or missed a 12 month visit or echo, 22 had MR > 2+
Conclusion: Significant measures of clinical benefit are observed one year following successful MitraClip therapy. A detailed analysis of the clinical data based on 12 month MR grade from the EVEREST II Randomized Clinical Trial will be presented.

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